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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,452	04/11/2001	Y. Tom Tang	PF-0619 USN	7669

7590

04/10/2003

Incyte Genomics
3160 Porter Drive
Palo Alto, CA 94304

EXAMINER

HELMS, LARRY RONALD

ART UNIT

PAPER NUMBER

1642

10

DATE MAILED: 04/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/807,452

Applicant(s)

TANG ET AL.

Examiner

Larry R. Helms

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature that appears to link the claims is a fragment of SEQ ID NO:2. Reference, WO 96/37611 (November 28, 1996) disclose a fragment of SEQ ID NO:2 (see the attached sequence alignment on the back of this Office Action). Therefore the technical feature recited in the claims is not a contribution over the prior art. Accordingly the groups set forth below are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Groups 1-17, claim(s) 1-2 and 15 in part, drawn to a polypeptide of SEQ ID NO:1-3, 5-13, 15-19, respectively (each group corresponds to a separate SEQ ID NO).

Groups 18-34, claim(s) 3-6, 9-14 in part, drawn to a polynucleotide encoding SEQ ID NO:1-3, 5-13, 15-19 or the polynucleotide of SEQ ID NO:21-32, 34-38 respectively (each group corresponds to a separate SEQ ID NO)..

Groups 35-51, claim(s) 7-8 in part, drawn to a method of detecting a polynucleotide that hybridizes with the complement of the nucleotide that encodes SEQ ID NO:1-3, 5-13, 15-19, respectively (each group corresponds to a separate SEQ ID NO).

Groups 52-68, claim(s) 16 in part, drawn to an antibody to SEQ ID NO:1-3, 5-13, 15-19, respectively (each group corresponds to a separate SEQ ID NO).

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Groups 69-85, claim(s) 17 in part, drawn to an agonist of SEQ ID NO:1-3, 5-13, 15-19, respectively (each group corresponds to a separate SEQ ID NO).

Groups 86-102, claim(s) 18 in part, drawn to an antagonist of SEQ ID NO:1-3, 5-13, 15-19, respectively (each group corresponds to a separate SEQ ID NO).

Groups 103-119, claim(s) claim 19 in part, drawn to a method of treating a disorder with decreased expression by administration of SEQ ID NO:1-3, 5-13, 15-19, respectively (each group corresponds to a separate SEQ ID NO).

Groups 120-136, claim(s) 20 in part, drawn to a method of treating a disorder with increased expression by administering an antagonist of SEQ ID NO:1-3, 5-13, 15-19, respectively (each group corresponds to a separate SEQ ID NO).

The inventions listed as Groups 1-136 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above in view of the teachings from the WO document the groups are not so linked as to form a single general concept under PCT Rule 13.1 because the technical feature shared by Groups 1-136 is not special.

Different products are presented in Groups 1-17, 18-34, 52-68, 69-85, 86-102. The products do not share a common core structure and in addition the polypeptides are all have different primary structures and as such an antibody or agonist or antagonist of one would not necessarily bind the other polypeptides or be antagonist or agonist of the other polypeptides. Groups 35-51, 103-119, 120-136 are methods that are distinct because each uses a distinct product as described above. In addition, Groups 35-51 uses a polynucleotide and Groups 103-119 uses a polypeptide and Groups 120-136

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uses an antagonist which does not require it to be either a polynucleotide or polypeptide. Thus the inventions 1-136 are patentably distinct.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different searches in the patent literature, restriction for examination purposes as indicated is proper.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (703) 306-5879. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the

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Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 308-4242.

Respectfully,

Larry R. Helms Ph.D.

703-306-5879

A handwritten signature in black ink, consisting of several overlapping, sweeping strokes that form a stylized representation of the name Larry R. Helms.

RESULT 2

AAW01750

ID AAW01750 standard; Protein; 268 AA.

XX

AC AAW01750;

XX

DT 04-SEP-1997 (first entry)

XX

DE EcoRI binding fragment protein 1 (EB1).

XX

KW EB1; EcoRI Binding Fragment protein 1; cellular; APC; truncation;
KW adenomatous polyposis coli; tumour suppressor; sporadic; familial;
KW colorectal cancer; predisposition; diagnosis; neoplasm; treatment.

XX

OS Homo sapiens.

XX

PN ~~QW09637611~~ A1.

XX

PD 28-NOV-1996.

XX

PF 22-MAY-1996; 96WO-US07747.

XX

PR 22-MAY-1995; 95US-0446919.

XX

PA (UYJO) UNIV JOHNS HOPKINS.

XX

PI Kinzier K, Vogelstein B, Kinzler K;

XX

DR WPI; 1997-021220/02.

DR

N-PSDB; AAT59331.

XX

PT EB1 DNA and polypeptide(s) - used to determine a pre-disposition to
PT or diagnose neoplasms and to assess treatment options.

XX

PS Claim 5; Page 19-21; 45pp; English.

XX

CC This sequence is that of an EB1 protein (EcoRI Binding Fragment protein
CC 1). This cellular protein associates with the carboxyl terminus of APC
CC (adenomatous polyposis coli) tumour suppressor gene product. The APC
CC tumour suppressor gene plays an important role in the development of both
CC sporadic and familial forms of colorectal cancers. Because most APC
CC mutations result in the truncation of the APC protein, these mutant APC
CC proteins cannot associate with EB1. This suggests that the interaction
CC between APC and EB1 is important for the normal function of APC and that
CC loss of this association is essential for the development of colorectal
CC cancer. By assaying for the presence of APC-EB1 protein complexes in a
CC cell, a predisposition to or diagnosis of neoplasms can be determined.
CC EB1 can also be used to assess treatment options for cancer cells (which
CC are good candidates for treatment with cyclooxygenase inhibitors).

XX

SQ Sequence 268 AA;

Query Match 61.0%; Score 909.5; DB 18; Length 268;

Best Local Similarity 64.6%; Pred. No. 8e-86;

Matches 186; Conservative 28; Mismatches 47; Indels 27; Gaps 6;

Qy 1 MAVNVYSTSVTSENLSRHDMLAWVNDLSHLNLTIEQLCSGAAYCQFMDMLFPGCVHLRK 60

Db 1 MAVNVYSTSVTSDNLSRHDMLAWINESLQLNLTKIEQLCSGAAYCQFMDMLFPGSIALKK 60

Qy 61 VKFQAKLEHEYIHNFKVLQAFAKKMGVDKIIPVEKLVKGFQDNFEFIQWFKKFFDANYD 120

Db 61 VKFQAKLEHEYIQNFKILQAGFKRMGVDKIIPVDKLVKGFQDNFEFVQWFKKFFDANYD 120

Qy 121 GKDYNP LLARQGDVAPPPNPGDQIFNKS KLI--GTAVPQRTSPT-----GPKNMQTS G 173

Db 121 GKDYDPVAARQGGQETAVAPSLVAPALNPKPKPLTSSSAAPQRPIS TQRTAAAPK----- 174

Qy 174 RLSNVAPPICILRKNPPSARNGGHETDAQILELNQQLVDLKLTV DGLEKERDFYFSKL RDI 233

Db 175 -----AGPGVVRKN-PGVGNG----DDEAAELMQQVNV LKLTVEDLEKERDFYFGKL RNI 224